



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health

- ☒ Preproposal Statement of Inquiry was filed as WSR 04-18-092 ; or
☒ Expedited Rule Making--Proposed notice was filed as WSR ; or
☒ Proposal is exempt under RCW 34.05.310(4).

- ☒ Original Notice
☒ Supplemental Notice to WSR
☒ Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

Chapter 246-239, Childbirth Centers. This chapter sets the minimum health and safety standards for the licensure and operations of childbirth centers in Washington State.

Hearing location(s):

Department of Health
Point Plaza East
Room 139
310 Israel Road NE
Tumwater, WA 98501

Submit written comments to:

Name: Yvette Fox

Address:

Post Office Box 47852
Olympia, WA 98504-7852
yvette.fox@doh.wa.gov

Web site: <http://www3.doh.wa.gov/policyreview/>

fax: (360) 236-2928 by (date) 10/10/2006

Date: 10/19/06 Time: 9:30 A.M.

Date of intended adoption: 10/26/2006

(Note: This is NOT the effective date)

Assistance for persons with disabilities: Contact

Yvette Fox by 10/10/2006

TTY (800) 833-6388 or () 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The purpose of the proposed rules is to more accurately reflect the childbirth center standards of practice within Washington State and nationally. The proposed rules include revisions such as clinical issues, consultative and transfer requirements, construction review requirements, patient rights, quality improvement, emergency preparedness, infection control and adverse event reporting.

Reasons supporting proposal:

The proposed rules set forth health and safety standards for childbirth centers as required of the Department of Health in chapter 18.46 RCW.

Statutory authority for adoption:

Chapter 18.46 RCW

Statute being implemented:

RCW 43.70.040

Is rule necessary because of a:

- Federal Law? ☐ Yes ☒ No
Federal Court Decision? ☐ Yes ☒ No
State Court Decision? ☐ Yes ☒ No

If yes, CITATION:

DATE

8/29/06

NAME (type or print)

Mary C. Selecky

SIGNATURE

TITLE

Secretary

CODE REVISER USE ONLY

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(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None

Name of proponent: (person or organization)

Department of Health

☐ Private

☐ Public

☒ Governmental

Name of agency personnel responsible for:

Name

Office Location

Phone

Drafting	Michael Johnson	PO Box 55517, Shoreline, WA 98155	(206)366-2638
Implementation	Byron Plan	310 Israel Road SE, Tumwater, WA 98501	(360)236-2916
Enforcement	Steve Saxe	310 Israel Road SE, Tumwater, WA 98501	(360)236-2902

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

☒ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name: Yvette Fox

Address:

Post Office Box 47852

Olympia, WA 98504-7852

phone: (360) 236-2928

fax: (360) 236-2901

e-mail: yvette.fox@doh.wa.gov

☐ No. Explain why no statement was prepared.

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes. A preliminary cost-benefit analysis may be obtained by contacting:

Name: Yvette Fox

Address:

Post Office Box 47852

Olympia, WA 98504-7852

phone: (360) 236-2928

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e-mail: yvette.fox@doh.wa.gov

☐ No. Please explain:

SMALL BUSINESS ECONOMIC IMPACT STATEMENT
For Rules Concerning Childbirth Centers
Chapter 246-329 WAC

Background

Chapter 18.46 RCW authorizes the Washington State Department of Health (DOH) to adopt rules to assure that minimum health and safety standards are set for childbirth centers. RCW 43.70.040 delegates authority to the Secretary of Health the power to administer and enforce these rules.

Rulemaking Requirements of the Regulatory Fairness Act (RCW 19.85)

The Regulatory Fairness Act, RCW 19.85.030 requires the department to conduct a Small Business Economic Impact Statement (SBEIS) for proposed rules that have more than minor impact on businesses within an industry. If a rule imposes disproportionate impact on small businesses an agency, where legal and feasible, must mitigate the costs to small businesses. As defined in RCW 19.85.020, a small business is "any business entity, including a sole proprietorship, corporation, partnership, or other legal entity, that is owned and operated independently from all other businesses, and that has fifty or fewer employees."

1. Briefly describe the proposed rule.

The proposed rules outline the minimum public health and safety standards for the licensure and operations of Childbirth Centers (CBC) in Washington State.

Minor Changes:

- Condense and clarify wording, grammar, structure and formatting
- Clarify requirements for licensing, reporting, documentation and compliance
- Remove issues unrelated to public health
- Update terminology to reflect current usage

Changes Easing Requirements:

The entire process involved the interested party community. The purpose was to more clearly state the rules for ease of use and understanding. The proposed rules more clearly state required processes to reflect the standard of practice within Washington State and nationally. The department utilized expert input, as well as national childbirth standards.

Changes Imposing Additional Requirements:

- Develop and implement written policies and procedures governing emergency preparedness and fire protection to align with standards for other like health care facilities.

- Maintain a quality improvement program to assure the quality of care and services provided result in continuous improvement of client health outcomes. Quality improvement requirements were stated in current rule, but the newly proposed requirements are more clearly stated and reflect contemporary standards for other like health care facilities.
- Provide each client with a written bill of rights, verified by client or representative signature, affirming each individual's rights and to align with standards for other like health care facilities.
- Notify and submit a written report to the department in the event of unanticipated death or loss of function, abduction or discharge to the wrong family, sexual assault or rape, or a catastrophic event to align with standards for other like health care facilities.

Other Components of the Rule:

- Allows birthing centers built before the adoption of proposed rules to be maintained to the standards that were in place at the time the facility was licensed. Modified or altered areas shall be maintained to the standards in place at the time that the modification or alteration was made and in accordance with the approved plans.

2. Is a Small Business Economic Impact Statement (SBEIS) required for this rule?

Yes, a SBEIS is required for this rule. The rule imposes more than \$66 on each facility, which is the median threshold for additional costs. There are 13 licensed childbirth centers in Washington State; each has less than 50 employees. The department surveyed each facility. The highest number of employees is six, the least number is one, for a median number of three. Therefore, there is not a disproportionate impact between small or large businesses.

3. Which industries are affected by this rule?

Childbirth centers are the only businesses impacted by these rules. There is no appropriate or specific Standard Industrial Classification (SIC) code for these businesses. Therefore, the department contacted each of the thirteen childbirth centers to verify the number of employees in each facility. All childbirth centers in Washington State meet the definition of a small business, having less than 50

4. What are the costs of complying with this rule for small businesses (those with 50 or fewer employees) and for the largest 10% of businesses affected?

NOTE: Additional estimated costs in Table 1 reflect a variance between one and six employees.

**Table 1
Rules with new fiscal impact**

<u>WAC</u>	<u>Annual Cost for Typical Small Business</u>	<u>Annual Cost for Typical Large Business</u>
246-329-085 Client Bill of Rights (one time only)	\$512	N/A
246-329-170 Emergency Preparedness (one time only)	\$32 - \$128	N/A
246-329-170 Emergency Preparedness	\$64	N/A
TOTAL	\$608-\$704	N/A

Table 2

Rules with potential new fiscal impact. Most childbirth centers already meet these requirements so the rule imposes no additional cost.

NOTE: Potential additional estimated costs in Table 2 reflect a variance of between one and six employees.

<u>WAC</u>	<u>Annual Cost for Typical Small Business</u>	<u>Annual Cost for Typical Large Business</u>
246-329-110 Personnel Policies and Procedures (one time only)	\$64-\$320	N/A
246-329-110 Personnel Policies and Procedures (training)	\$32-\$128	N/A
246-329-120 Birth Center Policies and Procedures (one time only)	\$320	N/A
246-329-140 Client Records (one time only)	\$500	N/A
246-329-180 Quality Improvement (one time only)	\$192	N/A
TOTAL	\$1108-\$1460	N/A

5. Does the rule impose a disproportionate impact on small businesses?

No. There are 13 licensed childbirth centers in Washington State. Each of them have less than 50 employees. The department surveyed each facility. The highest number of employees is six, the least number is one, for a median number of three. Therefore, there is not a disproportionate impact between small or large businesses. There are no large businesses; therefore, there is no disproportionate impact on small businesses.

6. If the rule imposes a disproportionate impact on small businesses, what efforts were taken to reduce that impact (or why is it not "legal and feasible" to do so) by

a) reducing, modifying, or eliminating substantive regulatory requirements?

- Clarify requirements for licensing, reporting, documentation and compliance
- Update terminology to reflect current usage

b) simplifying, reducing, or eliminating record keeping and reporting requirements?

Childbirth centers are currently required to have a defined client record system, policies and procedures. The proposed rule clarifies the type of documentation required. The proposed rule requires medical records to be maintained for a period of time, because it provides access to important medical information necessary to ensure continuity of care.

Accessible information could be invaluable in an emergent situation. The benefits of establishing a requirement to maintain information outweigh the costs associated with the proposed rule.

c) reducing the frequency of inspections?

The frequency of inspections is not addressed in the proposed rules.

d) delaying compliance timetables?

Although the department plans to offer statewide training on the proposed rules, no compliance delay is scheduled for its implementation.

e) reducing or modifying fine schedules for noncompliance?

Fine schedules for non-compliance are not addressed in the proposed rules.

f) any other mitigation techniques?

The Department of Health made every effort to mitigate any additional costs for childbirth centers throughout the rulemaking process. The department has also found that most childbirth centers already meet or exceed the proposed additional requirements; for those centers, additional costs will be nominal.

The proposed rules allow birthing centers built before the adoption of the rules to be maintained to the standards that were in place at the time the facility was licensed. This reduces the cost of the proposed rules to existing birth centers. If the department had not incorporated this change, the cost of requiring existing facilities to meet the proposed rules may have forced these businesses to close. Modified or altered areas are to be maintained to the standards in place at the time that the modification or alteration was made, and in accordance with the approved plans.

7. How are small businesses involved in the development of this rule?

Department staff worked closely with constituents, small businesses and the public to minimize the burden of this rule. The department notified all licensees and stakeholders when it first started developing the rule. Interested parties were invited to participate in a stakeholders workgroup including participants from all childbirth centers. Four stakeholder workgroup meetings were held in Olympia, Washington. The department also sought comment on draft language throughout the rule development process.

NEW SECTION

WAC 246-329-005 Scope and purpose. (1) These rules implement chapter 18.46 RCW which requires the department of health to set minimum health and safety standards for childbirth centers.

(2) Applicants and licensees must meet the requirements of this chapter and other applicable state and local laws.

(3) This chapter does not apply to services provided by persons exempt from requirements of chapter 18.46 RCW.

(4) A childbirth center may not provide services unless the childbirth center is licensed under this chapter.

AMENDATORY SECTION (Amending Order 224, filed 12/23/91, effective 1/23/92)

WAC 246-329-010 Definitions. For purposes of this chapter, the following words and phrases will have the following meanings unless the context clearly indicates otherwise:

(1) "Administration of drugs" means an act in which a single dose of a prescribed drug or biological is given to a client by an authorized person in accordance with all laws and ~~((regulations))~~ rules governing ~~((such))~~ these acts. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container, including a unit dose container, verifying it with the orders of a practitioner who is legally authorized to prescribe, giving the individual dose to the proper client and properly recording the time and dose given.

(2) "Applicant" means a person seeking licensure as a childbirth center under this chapter.

(3) "Authenticated or authentication" means authorization of a written entry in a record by means of a signature which shall include, minimally, first initial, last name, and title or unique identifier verifying accuracy of information.

~~((+3))~~ (4) "Bathing facility" means a bathtub or shower.

~~((+4))~~ (5) "((Birth)) Birthing center" or "childbirth center" or "birth center" means ((a type of maternity home which is a house, building, or equivalent organized to provide facilities and staff to support a birth service, provided that the birth service is limited to low-risk maternal clients during the intrapartum period)) any health facility, not part of a hospital or in a hospital, that provides facilities and clinical staff to support a birth service to low risk maternity clients. This chapter does not apply to any hospital approved by the American College of Surgeons,

American Osteopathic Association, or its successor.

((+5+)) (6) "Birthing room" means a room designed, equipped, and arranged to provide for the care of a woman and newborn and to accommodate her support person or persons during the process of vaginal childbirth, (the three stages of labor and recovery of a woman and newborn).

((+6+)) (7) "Birth service" means the prenatal, intrapartum, and postpartum care provided for ~~((individuals with uncomplicated pregnancy, labor, and vaginal birth))~~ low-risk maternity clients, ((to include the)) including newborn care during transition and stabilization.

((+7+)) (8) "Client" means a woman, fetus, and newborn receiving care and services provided by a birth center during pregnancy and childbirth and recovery.

((+8+)) (9) "Clinical staff" means physicians and midwives, including contractors, appointed by the governing body to practice within the birth center and governed by rules and policies and procedures approved by the governing body.

((+9+)) (10) "Consultation" means the process used by the clinical staff of a childbirth center who maintain primary management responsibilities for the client's care to seek the opinion of a licensed physician on clinical issues that are client specific. The physician consulted must be qualified by training and experience in specific client need for which consultation is sought. Consultation, appropriate to client need, must be available during all times birth services are provided in a childbirth center.

(11) "Contractor" means an individual who has a written contract with a birth center licensee to provide birth services. The written contract must be approved by the governing body, including appointment of clinical privileges by the governing body. Birth services provided by contractors in licensed birth centers must meet requirements of this chapter, unless otherwise noted.

(12) "Department" means the Washington state department of health.

((+10+)) (13) "Emergency" means a medical emergency or injury requiring immediate medical or surgical intervention to prevent death or disability.

(14) "Emergency transfer" means the transfer of a maternal client or newborn in an emergent situation to a facility that can manage obstetrical and neonatal emergencies, including the ability to perform cesarean delivery.

(15) "Governing body" means the person or persons responsible for establishing and approving the purposes and policies and procedures of the childbirth center.

((+11+)) (16) "Hospital" means any institution, place, building, or agency which provides accommodations, facilities, and services over a continuous period of twenty-four hours or more, for observation, diagnosis, or care, of two or more individuals not related to the operator or suffering from any other condition which obstetrical, medical, or surgical services would be appropriate for care or diagnosis. "Hospital" as used in this definition includes facilities licensed under chapter 70.41 RCW. "Hospital" as used in

this definition does not include:

(a) Hotels, or similar places furnishing only food and lodging, or simply, domiciliary care; ~~((nor does it include))~~

(b) Clinics ~~((or))~~ or physicians' offices where patients are not regularly kept as bed patients for twenty-four hours or more; ~~((nor does it include))~~

(c) Nursing homes, ((as defined and which comes)) defined and licensed under ((the scope of)) chapter 18.51 RCW; ~~((nor does it include maternity homes, which come within the scope of))~~

(d) Childbirth centers licensed under this chapter and chapter 18.46 RCW; ~~((nor does it include))~~

(e) Psychiatric hospitals, ((which come)) licensed under ((the scope of)) chapter 71.12 RCW; ~~((nor))~~ or

(f) Any other hospital or institution specifically intended for use and the diagnosis and care of those suffering from mental illness, mental retardation, convulsive disorders, or other abnormal mental conditions. ((Furthermore,)) Nothing in this definition shall be construed as authorizing the supervision, regulation, or control of the remedial care or treatment of residents or patients in any hospital conducted for those who rely primarily upon treatment by prayer or spiritual means in accordance with creed or tenets of any well-recognized church or religious denomination.

~~((+12))~~ (17) "Lavatory" means a plumbing fixture designed and equipped ((for handwashing purposes)) with a handwash device.

~~((+13))~~ (18) "Low-risk maternal client" means an individual who:

(a) Is at full-term gestation, in general good health with uncomplicated prenatal course and participating in ongoing prenatal care, and prospects for a normal uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health;

~~((b))~~ ((Is participating in an appropriate childbirth and infant care education program;

~~((c))~~ Has no major medical problems;

~~((d))~~ Has no previous major uterine wall surgery, ((caesarean)) cesarean section, or obstetrical complications likely to recur;

~~((e))~~ Has parity under six unless a justification for a variation is documented by clinical staff;

~~((f))~~ Is not a nullipara of greater than thirty-eight years of age unless a justification for a variation is documented by clinical staff;

~~((g))~~ Is not less than sixteen years of age unless a justification for variation for ages fourteen through fifteen only is documented by clinical staff;

~~((h))~~ (c) Has no significant signs or symptoms of anemia, active herpes genitalia, placenta praevia, known noncephalic presentation during active labor, pregnancy-induced hypertension, persistent polyhydramnios or persistent oligohydramnios, abruptio placenta, chorioamnionitis, known multiple gestation, intrauterine growth ((retardation, meconium stained amniotic fluid)) restriction, ((fetal complications,)) or substance abuse;

~~((i) Demonstrates no significant signs or symptoms of anemia, active herpes genitalis, pregnancy-induced hypertension, placenta praevia, malpositioned fetus, or breech while in active labor;~~
~~(j)) (d) Is in progressive labor (, progressing normally));~~
and

~~((k) Is without prolonged ruptured membranes;~~
~~(l) Is not in preterm labor nor postterm gestation;~~
~~(m) Is appropriate for a setting where analgesia is limited;~~
and

~~(n)) (e) Is appropriate for a setting where methods of anesthesia ((is used in)) are limited ((amounts and limited to local infiltration of the perineum or pudendal block)).~~

~~((14) "Maternity home" means any home, place, hospital, or institution in which facilities are maintained for the care of four or more women not related by blood or marriage to the operator during pregnancy or during or within ten days after delivery. Provided however, That this chapter shall not apply to any hospital licensed under chapter 70.41 RCW, "Hospital licensing and regulation."~~

~~(15)) (19) "Midwife" means ((an individual recognized by the Washington state board of nursing as a certified nurse midwife as provided in chapter 18.88 RCW, chapter 246-839 WAC, or an individual possessing a valid, current license to practice midwifery in the state of Washington as provided in)) a person licensed under chapter 18.79 RCW, or chapter 18.50 RCW, ((chapter 246-834 WAC)) Midwifery.~~

~~((16)) (20) "New construction" means any of the following:~~
~~(a) New buildings to be used as a birth center;~~
~~(b) Addition or additions to an existing building or buildings to be used as a childbirth center;~~
~~(c) Conversion of existing buildings or portions thereof for use as a childbirth center;~~
~~(d) Alterations or modifications other than minor alterations. "Minor alterations" means any structural or physical modification within an existing birth center which does not change the approved use of a room or an area. Minor alterations performed under this definition do not require prior review of the department; however, this does not constitute a release from other applicable requirements;~~
~~(e) Changes in the approved use of rooms or areas of the birth center.~~

~~((17)) (21) "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association, and the legal successor thereof.~~

~~(22) "Personnel" means individuals employed by the birth center, contractors of the birth center, students and volunteers.~~

~~((18)) (23) "Physician" means ((an individual)) a person licensed under ((provisions of)) chapter 18.71 RCW, "Physicians," and rules adopted under chapter 246-919 WAC or chapter 18.57 RCW, "Osteopathy--Osteopathic medicine and surgery((-))," and rules adopted under chapter 246-853 WAC.~~

~~((19)) (24) "Referral" means the process by which the clinical staff of a childbirth center directs the client to a~~

physician for management of a particular problem or aspect of the client's care.

~~((25))~~ (25) "Registered nurse" means ((an individual)) a person licensed under ((the provision of)) chapter ((18.88)) 18.79 RCW, ((("Registered nurses," who is practicing in accordance with the)) and rules ((and regulations promulgated thereunder)) adopted under chapter 246-840 WAC.

~~((26))~~ (26) "Recovery" means that period or duration of time starting at birth and ending with discharge of a client from the birth center or the period of time between the birth and the time a client leaves the premises of the birth center.

~~((27))~~ (27) "Shall" means compliance is mandatory.

~~((28))~~ (28) "Should" means a suggestion or recommendation, but not a requirement.

~~((29))~~ (29) "Support person" means the individual or individuals selected or chosen by a maternal client to provide emotional support and to assist her during the process of labor and childbirth.

~~((30))~~ (30) "Toilet" means a room containing at least one water closet.

~~((31))~~ (31) "Transfer of care" means the process by which the clinical staff of a childbirth center directs the client or newborn to a physician or other licensed health care provider for complete management of client's care. Transfer of care to an appropriate obstetrical department, patient care area or hospital, or physician(s) qualified in obstetrics or newborn/pediatric care respectively with admitting privileges to a hospital must be available twenty-four hours per day.

~~((32))~~ (32) "Volunteer" means an individual who is an unpaid worker in the birth center, other than a support person.

~~((33))~~ (33) "Water closet" means a plumbing fixture for defecation fitted with a seat and a device for flushing the bowl of the fixture with water.

AMENDATORY SECTION (Amending Order 224, filed 12/23/91, effective 1/23/92)

WAC 246-329-020 Licensure. ((1) Application for license.

~~(a) An application for a childbirth center license shall be submitted on forms furnished by the department. The application shall be signed by the legal representative of the governing body.~~

~~(b) The applicant shall furnish to the department full and complete information and promptly report any changes which would affect the current accuracy of such information as to the identity of each officer and director of the corporation, if the birth center is operated by a legally incorporated entity, profit or nonprofit, and of each partner if the birth center is operated through a legal partnership.~~

(c) Each application for license shall be accompanied by a license fee as established by the department under RCW 43.70.110. Provided, That no fee shall be required of charitable or nonprofit or government-operated birth centers. Upon receipt of the license fee, when required, the department shall issue a childbirth center license if the applicant and the birth center facilities meet the requirements of this chapter.)) A person must possess a current birth center license issued by the department before advertising, operating, managing, conducting, opening or maintaining a childbirth center unless exempt under chapter 18.46 RCW.

(1) Application for license. An applicant for initial licensure of a childbirth center must:

(a) Submit a completed application on forms provided by the department;

(b) Submit disclosure statements and criminal history background checks no older than three months preceding the application date for the administrator, owner and director of services in accordance with RCW 43.43.830 through 43.43.845;

(c) Submit the following information:

(i) Name of managing personnel, officers, administrator, director of clinical services or supervisor of clinical services, and partners or individuals owning ten percent or more of the applicant's voting stock;

(ii) A description of the organizational structure;

(iii) Name, address, and phone numbers of all office locations that provide services within the state;

(iv) A copy of the current business license(s);

(d) Submit evidence of completion of the department's construction review process;

(e) Submit evidence of compliance with local codes and ordinances;

(f) Submit evidence of approval of the state fire marshal as required per RCW 18.46.110;

(g) Submit evidence that a certificate of occupancy by the local building official has been approved and issued;

(h) Submit other information as required by the department;

(i) Submit fees as specified in WAC 246-329-990;

(j) Furnish to the department full and complete information and promptly report any changes which would affect the current accuracy of this information as to the identity of each officer and director of the corporation, if the birth center is operated by a legally incorporated entity, profit or nonprofit, and of each partner if the birth center is operated through a legal partnership;

(k) Develop and approve policies and procedures addressing the content of this chapter; and

(1) Meet the requirements of this chapter as determined by an initial survey conducted by the department.

(2) License renewal(~~((--Limitations--Display))~~).

(a) A license, unless suspended or revoked, shall be renewed annually.

((~~(+)~~)) Applications for renewal (~~((shall))~~) must be on forms provided by the department and (~~((shall))~~) must be filed with the

department not less than ~~((ten))~~ thirty days prior to expiration and must also include disclosure statements and criminal history background checks no older than three months preceding the renewal date for the administrator, owner and director of services when these individuals are new to the birth center since initial licensure or last renewal, in accordance with RCW 43.43.830 through 43.43.845.

~~((fii))~~ (b) The department ~~((shall))~~ may inspect and investigate each childbirth center every twenty-four months or as needed ~~((and at least annually))~~ to determine compliance with ~~((standards herein (chapter 246-329 WAC) and applicable standards of))~~ these rules and chapter 18.46 RCW.

~~((b7))~~ (c) Each license shall be issued only for the premises and persons named. Licenses shall be transferrable or assignable only with written approval by the department.

~~((c))~~ (d) Licenses ~~((shall))~~ must be posted in a conspicuous place on the licensed premises.

(3) ~~((Denial, suspension, modification, revocation of a license, notice, adjudicative proceeding.~~

~~(a) The department may, if the interests of the clients so demand, deny, suspend, or revoke a license when there has been failure or refusal to comply with the requirements of chapter 18.46 RCW and/or these rules. The department's notice of a denial, suspension, modification, or revocation of a license shall be consistent with RCW 43.70.115. An applicant or license holder has the right to an adjudicative proceeding to contest the decision.~~

~~(b) A license applicant or holder contesting a department license decision shall within twenty-eight days of receipt of the decision:~~

~~(i) File a written application for an adjudicative proceeding by a method showing proof of receipt with the Administrative Hearings Unit, Department of Health, 1300 Quince Street S.E., P.O. Box 47851, Olympia, WA 98504-7851, and~~

~~(ii) Include in or with the application:~~

~~(A) A specific statement of the issue or issues and law involved;~~

~~(B) The grounds for contesting the department decision; and~~

~~(C) A copy of the contested department decision.~~

~~(c) The proceeding is governed by the Administrative Procedure Act (chapter 34.05 RCW), this chapter, and chapter 246-08 WAC. If a provision in this chapter conflicts with chapter 246-08 WAC, the provision in this chapter governs.~~

~~(4) New construction--Major alterations.~~

~~(a) When new construction or major alteration is contemplated, the following shall be submitted to the department for review:~~

~~(i) A written program containing, at a minimum, information concerning services to be provided and operational methods to be used which will affect the extent of facilities required by these regulations;~~

~~(ii) Duplicate sets of preliminary plans which are drawn to scale and include: A plot plan showing streets, driveways, water, and sewage disposal systems, grade and location of the building or buildings on the site, the plans for each floor of each building,~~

~~existing and proposed, which designate the functions of each room and show all fixed equipment. The preliminary plans shall be accompanied by a statement as to the source of water supply and the method of sewage and garbage disposal and a general description of construction and materials, including interior finishes.~~

~~(b) Construction shall not be started until duplicate sets of final plans (drawn to scale) and specifications have been submitted to and approved by the department. Final plans and specifications shall show complete details to be furnished to contractors for construction of buildings or major alterations in existing buildings. These shall include:~~

- ~~(i) Plot plans;~~
- ~~(ii) Plans for each floor of each building which designate the function of each room and show all fixed equipment and the planned location of beds and other furniture;~~
- ~~(iii) Interior and exterior elevations, building sections, and construction details;~~
- ~~(iv) Schedule of floors, wall, and ceiling finishes, and the types and sizes of doors and windows, plumbing, heating, ventilation, and electrical systems; and~~
- ~~(v) Specifications which fully describe workmanship and finishes.~~

~~(c) Adequate provisions shall be made for the safety and comfort of clients as construction work takes place in or near an occupied area.~~

~~(d) Construction shall take place in accordance with approved final plans and specifications. Only those changes which have been approved by the department may be incorporated into the construction project. Modified plans, additions, or changes incorporated into the construction project shall be submitted to the department for the department file on the project.~~

~~(5) Compliance with other regulations.~~

~~(a) Applicable rules and regulations adopted by the Washington state fire marshal.~~

~~(b) If there is no local plumbing code, the Uniform Plumbing Code of the National Association of Plumbing and Mechanical Officials shall be followed.~~

~~(c) Compliance with these regulations does not exempt birth centers from compliance with the local and state electrical codes or local fire, zoning, building, and plumbing codes.)~~ Change of ownership. At least thirty days prior to changing ownership of a childbirth center:

(a) The licensee must submit in writing to the department:

(i) The full name, address and phone number of the current and prospective owner;

(ii) The name, address, and phone number of the currently licensed childbirth center and the name under which the prospective agency will operate;

(iii) Date of the proposed change of ownership; and

(iv) Any changes in the office location, if relevant;

(b) The prospective new owner must submit:

(i) Information listed in subsection (1)(b) through (c) of this section; and

- (ii) The change of ownership fee specified in WAC 246-329-990.

NEW SECTION

WAC 246-329-025 Exemptions, alternative methods, and interpretations. The purpose of this section is to provide birth centers a mechanism to request an interpretation, exemption, or approval to use an alternative method. This chapter is not intended to prevent use of any systems, materials, alternate design, or methods of construction as alternatives to those prescribed by these rules.

(1) A birth center requesting exemption from this chapter must submit a written request to the department asking for an exemption. The request must specify the section or sections, explain the reason for the exemption and, when appropriate, include supporting documentation.

(2) A birth center requesting approval for use of alternative materials, design, and methods must submit a written request to the department asking for approval to use an alternative. The request must explain the reason(s) for the use of an alternative and must be supported by technical documentation.

(3) The department may:

(a) Exempt a birth center from complying with portions of this chapter when:

(i) The exemption is not contrary to the intent of chapter 18.46 RCW and the requirements of these rules.

(ii) After review and consideration, the department determines the exemption will not:

(A) Negate the purpose and intent of these rules;

(B) Place the safety or health of the patients in the birth center in jeopardy;

(C) Lessen any fire and life safety or infection control provision of other codes or regulations; and

(D) Affect any structural integrity of the building;

(b) Approve the use of alternative materials, designs, and methods when:

(i) The birth center complies with subsection (2) of this section; and

(ii) After review and consideration, such alternative:

(A) Meets the intent and purpose of these rules; and

(B) Is at least equivalent to the methods prescribed in these rules.

(4) A birth center requesting an interpretation of rule contained in this chapter must submit a written request to the department. The request must specify the section or sections for which an interpretation is needed and details of the circumstances to which the rule is being applied. The birth center must provide any other information the department deems necessary.

(5) The department will, in response to a written request, send a written interpretation of a rule or regulation within thirty calendar days after the department has received complete information relevant to the requested interpretation.

(6) The department and birth center will keep a copy of each exemption or alternative granted or interpretation issued under this section on file and available at all times.

AMENDATORY SECTION (Amending Order 224, filed 12/23/91, effective 1/23/92)

WAC 246-329-030 (~~Governing body and administration.~~)
Governance. The purpose of this section is to provide organizational guidance and oversight and to ensure resources and staff to support safe and adequate patient care.

(1) The birth center shall have a governing body.

(2) The governing body shall be responsible for (~~provision of~~) providing personnel, facilities, equipment, supplies, and special services (~~needed~~) to meet the needs of the clients.

(3) The governing body shall adopt policies for the care of clients within or on the premises of the birth center.

(4) The governing body shall appoint an administrator or director (~~who shall be~~) responsible for implementing the policies adopted by the governing body.

(5) The governing body shall establish and maintain a current written organizational plan which includes all positions and delineates responsibilities, authority, and relationship of positions within the birth center.

(6) The governing body shall have the authority and responsibility for appointments and reappointments of clinical staff, approval of written contracts and appointment of contractors, approval of clinical bylaws and to ensure that only members of the clinical staff (~~shall~~) admit clients to the birth center.

(a) Each birth center shall have (~~designated~~) access to physician ((participation in)) consultation and appropriate clinical services ((and in the quality assurance program)) as defined in WAC 246-329-095(2).

(b) (~~Each birth center shall have a written policy and program which shall stipulate the extent of physician participation in the services offered.~~

(~~c~~)) Each physician and midwife, including contractors, appointed to the clinical staff shall provide evidence of current licensure in the state of Washington.

(~~d~~)) (c) Members of the clinical staff shall develop and adopt bylaws, ((rules, and regulations)) policies, and procedures subject to the approval of the governing body ((which shall include)) including requirements for clinical staff membership;

delineation of clinical privileges and the organization of clinical staff.

(7) The governing body shall be responsible for assuring a quality (~~assurance audit on a regular basis to review cases, minimally to include ongoing compliance with rules in chapter 246-329-WAC~~) improvement program is implemented according to WAC 246-329-180.

(8) The governing body shall have responsibility for the legal and financial management of the birth center.

NEW SECTION

WAC 246-329-045 Applicant or licensee rights and responsibilities. This section describes the applicant or licensee's responsibilities in the fulfillment of the requirements of this chapter.

- (1) An applicant or licensee must:
 - (a) Comply with chapter 18.46 RCW and this chapter;
 - (b) Establish, implement and periodically review all policies and procedures which address the contents of this chapter;
 - (c) Display the license issued by the department in an area accessible to the public;
 - (d) Notify the department in writing:
 - (i) Within thirty days of changes of an administrator, owner or the director of clinical services;
 - (ii) Thirty or more days before ceasing operations;
 - (e) Cooperate with the department during surveys which may include reviewing licensee and client records and conducting client interviews with client consent;
 - (f) Respond to a statement of deficiencies by submitting to the department:
 - (i) A written plan of correction, within ten working days of receipt. The applicant or licensee must complete all corrections within sixty days after the survey exit date, unless otherwise specified by the department; and
 - (ii) A progress report describing corrections made and ongoing monitoring actions, within ninety days after the survey exit date, unless the department specifies another date.
- (2) An applicant or licensee may:
 - (a) Discuss findings observed during a survey with the surveyor; and
 - (b) Discuss the statement of deficiencies with the department's manager.
- (3) As required by chapter 70.56 RCW, the licensed childbirth center shall notify the department if any of the following events have been confirmed to have occurred in the birth center:
 - (a) An infant abduction or discharge to the wrong family;
 - (b) Sexual assault or rape of a patient or staff member while

in the birth center;

(c) Maternal death or serious disability with labor or delivery in a low-risk pregnancy while being cared for in a health care facility;

(d) Patient death or serious disability associated with:

(i) The use of contaminated drugs, devices, or biologics provided by the health care facility;

(ii) The use or function of a device in which the device is used or functions other than as intended;

(iii) Intravascular air embolism that occurs while being cared for in a health care facility;

(iv) A medication error (errors involving wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration);

(v) Hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility;

(vi) Failure to identify and treat hyperbilirubinemia in neonates;

(vii) An electric shock while being cared for in a health care facility; or

(viii) A burn incurred from any source while being cared for in a health care facility.

(e) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;

(f) Patient suicide, or attempted suicide resulting in serious disability, that occurs while the patient is receiving care in a health care facility;

(g) Death or significant injury of a patient or staff member resulting from physical assault that occurs within or on the grounds of a health care facility;

(h) Any instance of care ordered by someone impersonating a physician, nurse, pharmacist or other licensed health care provider;

(i) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility;

(j) Patient death associated with a fall while being cared for in a health care facility;

(k) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility; and

(l) Sexual assault on a patient within or on the grounds of a health care facility.

(4) The licensed childbirth center must also notify the department if either of the following events have been confirmed to have occurred in the birth center:

(a) An unanticipated death, stillbirth or major loss of function; or

(b) Any catastrophic incident, such as fire or flood, or any incident which may cause interruption or cessation of the delivery of services, or another interruption of services which would affect the health and safety of the client.

(5) The report required in subsection (3) and (4) of this section must be submitted in writing to the department as required by chapter 70.56 RCW. The birth center is encouraged to confirm these events through a review or assessment by the birth center's quality improvement or risk management process. Each notice to the department must include:

- (a) The licensee's name;
- (b) The name of the affected client, if applicable;
- (c) The date the event occurred;
- (d) A description of the event and a clinical summary if the event is client-related;
- (e) Root cause analysis and corrective action plans as required by chapter 70.56 RCW.

(6) The report note in subsection (3) of this section:

(a) Will allow the department to be informed of events which in the interest of the public will be reviewed and reported as required by chapter 70.56 RCW;

(b) Will be confidentially maintained by the department in accordance with the protections of the Public Disclosure Act, chapter 42.17 RCW, and other applicable laws and reporting requirements; and

(c) Does not relieve a birth center from complying with other applicable reporting or notification requirements of this chapter or those requirements relating to law enforcement or professional regulatory agencies.

(7) An applicant or licensee has the right to respond to and contest a statement of charges according to the following provisions:

(a) RCW 43.70.115, department of health authority for license approval, denial, restriction, conditioning, modification, suspension and revocation;

(b) Chapter 34.05 RCW, the Administrative Procedure Act; and

(c) Chapter 246-10 WAC, Adjudicative proceedings.

NEW SECTION

WAC 246-329-055 Department responsibilities. This section describes the department's responsibilities in the fulfillment of the requirements of this chapter:

(1) The department may, in accordance with chapter 18.46 RCW:

(a) Issue an initial license for twelve months following submission of a completed application and appropriate fee, and following a survey that documents the applicant meets all the requirements of this chapter;

(b) Issue a renewal license for the twelve-month period following submission of a completed application and appropriate fee;

(c) Issue a license for change of ownership to the new licensee

for the remainder of the current license period following submission of the required information and appropriate fee, under WAC 246-329-990.

(2) The department may:

(a) Conduct surveys and investigations every twenty-four months or as needed to determine compliance with chapter 18.46 RCW and this chapter. Surveys and investigations may be announced or unannounced;

(b) Investigate any person suspected of:

(i) Advertising, operating, managing, conducting, opening or maintaining a childbirth center without a license unless exempt from licensure under chapter 18.46 RCW; or

(ii) Survey a licensee at anytime if the department has reason to believe the licensee is providing unsafe, insufficient, inadequate or inappropriate care;

(c) Investigate allegations of noncompliance with RCW 43.43.830 through 43.43.845, when necessary, in consultation with law enforcement personnel;

(d) Require licensees to complete additional disclosure statements and background inquiries for an individual associated with the licensee or having direct contact with children under sixteen years of age, people with developmental disabilities, or vulnerable adults if the department has reason to believe that offenses specified under RCW 43.43.830 have occurred since completion of the previous disclosure statement and criminal background inquiry; and

(e) Issue a statement of deficiencies following a survey which identifies noncompliance with chapter 18.46 RCW and this chapter.

(3) The department may deny, suspend, or revoke a license if the applicant or licensee fails or refuses to comply with the requirements of chapter 18.46 RCW and/or these rules. The department's notice of denial, suspension, modification, or revocation of a license shall be consistent with RCW 43.70.115. An applicant or license holder has the right to an adjudicative proceeding to contest the decision.

(4) The department may prepare and serve upon the licensee or applicant at the earliest practical time a statement of charges following a survey which identifies noncompliance with chapter 18.46 RCW and this chapter. The statement of charges must include a notice that the licensee or applicant may request a hearing to contest the charges.

NEW SECTION

WAC 246-329-065 New construction--Major alterations. The purpose of this section is to provide minimum standards for a safe and efficient patient care environment consistent with other rules. The rules are intended to allow flexibility in achieving desired

outcomes and enable birth centers to respond to changes in technologies and health care innovations.

(1) When a licensee or applicant is contemplating new construction or major alteration, the licensee or applicant shall:

(a) Under chapters 70.40 RCW and 246-329 WAC, submit an application and construction documents to the department's construction review services program for all new construction and major alterations, as defined in WAC 246-329-010. In addition to the application and construction documents, the construction review services program may require documentation of approval from local zoning commissions, fire departments, and building departments, if applicable;

(b) Respond in writing when the department requests additional or corrected construction documents;

(c) Not begin construction until the construction documents are approved by the local jurisdictions and same local jurisdictions have issued any required permits;

(d) Complete construction consistent with the final "department approved" documents;

(e) Notify the department in writing when construction is completed; and

(f) Submit to the department a copy of the local jurisdictions' certificate of occupancy.

(2) A childbirth center applicant or licensee must, through its design, construction and necessary permits demonstrate compliance with the following codes and local jurisdiction standards:

(a) The state building code as adopted by the state building code council.

(b) *Accepted Procedure and Practice in Cross-contamination Control, Pacific Northwest Edition, 9th Edition, American Waterworks Association*; and

(c) If planning on caring for patients with mycobacterium tuberculosis, *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities, 1994. Morbidity and Mortality Weekly Report (MMWR), Volume 43, October 28, 1994.*

NEW SECTION

WAC 246-329-075 Criminal history, disclosure, and background inquiries. The purpose of this section is to ensure criminal history background inquiries are conducted for any employee or prospective employee who has or will have unsupervised access to children, vulnerable adults, and individuals with developmental disabilities.

(1) A childbirth center applicant or licensee must establish and implement policies and procedures regarding Washington state

patrol criminal background inquiries and disclosure statements under RCW 43.43.830 through 43.43.845 for the administrator, owner, director of services and personnel, contractors, volunteers, students, and any other individual associated with the licensee having direct contact with children under sixteen years of age, individuals with developmental disabilities, or vulnerable adults.

(2) The department may require licensees to complete additional disclosure statements or background inquiries for a person associated with the licensed facility having direct contact with vulnerable adults if the department has reason to believe that offenses specified under RCW 43.43.830 have occurred since completion of the previous disclosure statement or background inquiry.

NEW SECTION

WAC 246-329-085 Client bill of rights. The purpose of this section is to help improve patient outcomes by respecting each client and conducting all relationships with clients and the public in an ethical manner.

The birth center at the time of registration, including clients of contractors, must provide each client with a written bill of rights, verified by client or representative signature, affirming each individual's rights to:

(1) A listing of the services provided by the birth center and a description of other levels of maternal/fetal services available in the community;

(2) Be informed of the policy and procedures for admission and discharge;

(3) Be informed of the definition of a low risk maternal client, the benefits and risks of out-of-hospital labor and birth and complete a written informed consent, prior to the onset of labor that shall include, but not be limited to, evidence of an explanation by personnel of the birth services offered and potential risks and emergency transfer and transport procedures;

(4) Be informed of what constitutes being ineligible for birth center services and the transfer policy and procedures of clients who, during the course of pregnancy or labor or recovery, are determined to be ineligible, including the birth center's plan for provisions of emergency and nonemergency care in the event of complications to mother and newborn;

(5) Be informed that unexpected neonatal emergencies requiring complex resuscitation are rare, but can occur. Be informed that the birth center staff is prepared to provide initial steps of newborn resuscitation (upper airway clearance with a bulb or mechanical suction) and provide bag-and-mask ventilation until emergency medical service providers arrive to provide complete resuscitation procedures if required;

(6) Participate in decisions relating to the plan for management of care and all changes in that plan once established including consultation, referral and transfer to other practitioners or other levels of care;

(7) Be informed of the policy and procedures for consultation, referral, transfer of care and transport of a newborn and maternal client to a hospital where appropriate care is available;

(8) Be informed of prenatal screening under chapter 70.54 RCW and chapter 246-680 WAC;

(9) Be informed of newborn screening requirements under chapter 70.83 RCW and chapter 246-650 WAC, including a provision of a copy of the parent information pamphlet "Newborn Screening Tests and Your Baby" which is available from the department's newborn screening program;

(10) Be informed that rapid HIV testing is available for all maternal clients without a documented history of HIV testing during prenatal care;

(11) Be informed of prophylactic treatment of the eyes of the newborn in accordance with WAC 246-100-206 (6) (b);

(12) Be informed that vitamin K administration for the newborn is available;

(13) Be informed that newborn hearing screening tests are offered in most hospitals;

(14) A description of the process for submitting and addressing complaints;

(15) Submit complaints without retaliation and to have the complaint addressed by the licensee;

(16) Be informed of the state complaint hotline number;

(17) Be treated with courtesy, dignity, respect, privacy, and freedom from abuse and discrimination;

(18) Refuse treatment or services;

(19) Privacy of personal information and confidentiality of health care records;

(20) Be cared for by properly trained personnel, contractors, students and volunteers and be informed of the qualifications of clinical staff, consultants and related services and institutions;

(21) Be informed of all diagnostic procedures and reports, recommendations and treatments;

(22) A fully itemized billing statement upon request, including the date of each service and the charge;

(23) Be informed about advanced directives and the licensee's responsibility to implement them;

(24) Be informed of the client's right with regards to participation in research or student education programs;

(25) Be informed of the liability insurance coverage of practitioners on request; and

(26) Be informed of child passenger restraint systems to be used when transporting children in motor vehicles, including information describing the risks of death or serious injury associated with the failure to use a child passenger restraint system.

NEW SECTION

WAC 246-329-095 Staffing. The purpose of the staffing section is to ensure the birth center provides competent staff consistent with the scope of services.

(1) The birth center shall have sufficient, qualified personnel and clinical staff to provide the services needed by clients and for safe maintenance and operation of the birth center.

(2) The birth center shall have written plans for consultation, referral, transfer of care, emergency transfer and transport of a newborn to a newborn nursery or neonatal intensive care nursery, and emergency transfer or transport of a maternal client to an appropriate obstetrical department, patient care area or hospital where appropriate care is available.

(3) The birth center shall:

(a) Employ, contract or use appropriately trained personnel and clinical staff; and

(b) Assure clinical staff or personnel have evidence of current training in neonatal and adult resuscitation.

(c) Assure a physician or midwife is present at each birth. A second person who is an employee, student or member of the clinical staff with evidence of current training in neonatal and adult resuscitation skills shall be immediately available in the birthing center during each birth.

(d) Ensure twenty-four hour coverage, including the provision that appropriate, qualified personnel and/or clinical staff shall be present in the birth center at all times when clients are present.

NEW SECTION

WAC 246-329-110 Personnel policy and procedures and records. The purpose of this section is to ensure the birth center provides direction and standards in the employment, contracting and recording of personnel procedures.

(1) A childbirth center applicant or licensee must establish and implement policy and procedures which include, but are not limited to:

(a) For those birth centers operated by an employer as defined by RCW 49.60.040(3), employment criteria consistent with chapter 49.60 RCW;

(b) Job descriptions for employees, contractor agreements, volunteer responsibility statements and agreements with students commensurate with responsibilities and consent with health care professional credentialing and scope of practice as defined in relevant practice acts and associated rules;

(c) Verification of clinical staff credentials;

(d) Orientation to current agency policies and procedures and

verification of skills or training for all clinical staff;

(e) Current neonatal and adult cardiopulmonary resuscitation training consistent with agency policies and procedures and community standards for all clinical staff;

(f) Infection control practices for clinical staff including communicable disease testing, immunization, vaccination and universal precautions or equivalent method of preventing the transmission of infection according to current local health authorities and shall include the availability of equipment necessary to implement plans of care and infection control policies and procedures;

(i) Birth centers must establish and implement a TB screening program for personnel;

(ii) Birth centers must provide or offer to employees Hepatitis B vaccination according to WAC 296-62-08001; and

(iii) Birth centers must assure that all contractors have received or been offered Hepatitis B vaccination according to WAC 296-62-08001;

(g) Verification of appropriate education and training of all personnel, contractors, student and volunteers on the prevention, transmission, and treatment of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) consistent with RCW 70.24.310;

(h) Performance evaluations of all personnel, including evaluations of contractor and student agreements to be conducted per birth center's policy and procedure; and

(i) Washington state patrol criminal background inquiries and disclosure statements under RCW 43.43.830 through 43.43.845 for the administrator, owner, director of services and personnel, contractors, volunteers, students, and any other individual associated with the licensee who has direct contact with children under sixteen years of age, people with developmental disabilities or vulnerable adults.

(2) Each employee, contractor, student and volunteer shall have a current record maintained by the birth center which contains, but is not limited to, the following information:

(a) Documentation of the items stated above in subsection (1)(b) through (e) and (g) through (i) of this section.

(b) Evidence of communicable disease testing as required by local health authorities and per birth center policy and procedures and shall include, at a minimum, documented evidence of tuberculin (TB) screening as required in WAC 246-329-110 (1)(f) and documented evidence of Hepatitis B vaccination being provided or offered according to WAC 296-62-08001.

NEW SECTION

WAC 246-329-120 Birth center policies and procedures. The purpose of this section is to ensure the birth center is able to provide safe and appropriate care to the clients of the birth center.

(1) An applicant or licensee must establish and implement policy and procedures which include, but are not limited to:

(a) Definition of a low-risk maternal client who is eligible for birth services offered by the birth center.

(b) Definition of a client who is ineligible for birth services at the birth center.

(c) Identification and transfer of clients who, during the course of pregnancy, are determined to be ineligible.

(d) Identification and transfer of clients who, during the course of labor or recovery, are determined to be ineligible for continued care in the birth center.

(e) Written plans for consultation, referral and transfer of care for maternal client and newborn. Written plans for emergency transfer and transport of a newborn to a newborn nursery or neonatal intensive care nursery, and emergency transfer and transport of a maternal client to an appropriate obstetrical department, patient care area, or hospital where appropriate care is available.

(f) Transfer and discharge of neonates to minimize risk of newborn abduction.

(g) Protocol for medications and laboratory testing during labor and recovery if the birth center plans to deliver HIV positive clients.

(h) Rapid HIV testing using the opt out approach for women who have undocumented HIV test results when presenting to the birth center in labor.

(i) Protocol for electronic fetal heart monitoring or intermittent auscultation to monitor fetal status during labor.

(j) Protocol for the provision of MMR vaccine to nonimmune postpartum women.

(k) Protocol for the provision of anti D immune globulin to postpartum women who are unsensitized D-Negative and who deliver a D positive or Du positive infant.

(2) The applicant or licensee shall assure that transfer of care shall be available twenty-four hours per day to an appropriate obstetrical department, patient care area, or hospital where appropriate care is available.

(3) Clients shall receive and sign written informed consent which shall be obtained prior to the onset of labor and shall include, but is not limited to:

(a) Evidence of an explanation by personnel of the birth services offered, limitation of services, and potential risks;

(b) Explanation of the definition of low-risk maternal client;

(c) Explanation of a client who is ineligible for childbirth center services;

(d) Explanation of the birth center policies and procedures

for consultation, referral, transfer of care and emergency transfer and transport;

(e) Explanation of prophylactic treatment of the eyes of the newborn in accordance with WAC 246-100-206 (6) (b);

(f) Explanation of screening of newborns under chapter 70.83 RCW and chapter 246-650 WAC; and

(g) Explanation of why rapid HIV testing is available if documentation of an HIV test during prenatal care is not available;

(h) Explanation of the need for prophylactic administration of RhIG (immune globulin) within seventy-two hours of delivery for an Rh negative mother whose newborn(s) are Rh positive.

(4) The birth center shall provide or assure:

(a) Education of clients, family and support persons in childbirth and newborn care.

(b) Plans for immediate and long-term follow-up of clients after discharge from the birth center.

(c) Registration of birth and reporting of complications and anomalies, including sentinel birth defect reporting under chapter 70.58 RCW.

(d) Prophylactic treatment of the eyes of the newborn in accordance with WAC 246-100-206 (5) (b).

(e) Collection of a newborn screening blood specimen, or signed refusal, and submission to the department's newborn screening program under the requirements of WAC 246-650-020.

(f) Rapid HIV testing when documentation of an HIV test during prenatal care is not available, unless the client refuses to give consent and the refusal is documented.

(g) For HIV positive women, the antiretroviral medications during delivery and perform or arrange appropriate lab tests.

(h) Intrapartum intravenous antibiotics for Group B Strep positive women per the CDC protocol.

(i) For Hepatitis B positive women, HBIG and Hepatitis B immunization for the newborn.

(j) Infection control to housekeeping; cleaning, sterilization, sanitization, and storage of supplies and equipment, and health of personnel and clients.

(k) Actions to take when personnel, volunteers, contractors, or patients or clients exhibit or report symptoms of a communicable disease in an infectious stage in accordance with chapter 246-100 WAC, Communicable and certain other diseases and chapter 246-101 WAC, Notifiable conditions.

(l) Authorization and administration of medications, legend drugs and devices per appropriate health profession rules.

(m) Actions to address patient or client communication needs.

(n) Reporting of patient/client abuse and neglect according to chapter 74.34 RCW.

(o) Emergency care of client.

(p) Actions to be taken upon death of a client.

(q) Plans for service delivery when natural or man-made emergencies occur that prevent normal clinical operation.

(r) Waived laboratory tests, if applicable, including the procurement of a medical test site waiver under chapter 246-338 WAC.

NEW SECTION

WAC 246-329-130 Birth center equipment and supplies. The purpose of this section is to ensure the birth center provides safe and appropriate equipment and supplies necessary to the safe provision of care to the client of the birth center.

(1) The applicant or licensee shall assure the birth center has the adequate, appropriate size and type equipment and supplies maintained for the maternal client and the newborn to include:

- (a) A bed suitable for labor, birth, and recovery;
- (b) Separate oxygen with flow meters and masks or equivalent;
- (c) Suction equipment for the maternal client and newborn to include suction apparatus, either operated from a wall outlet or portable equipment, and bulb suction as appropriate. These devices must be immediately available in the birth center;

- (d) Resuscitation equipment to include adult and neonate resuscitation bags and term and preterm size face masks, and neonatal-sized oxygen bags for assisted ventilation. Newborn resuscitation equipment shall include method to deliver free flow oxygen;

- (e) Firm surfaces suitable for resuscitation;

- (f) Fetal monitoring equipment, minimally to include a fetoscope, doppler or electronic monitor;

- (g) Equipment for monitoring and maintaining the optimum body temperature of the newborn. A heat source appropriate for use in warming newborns shall be available, and may include an incubator;

- (h) A time keeping device;

- (i) Sterile suturing equipment and supplies;

- (j) Glucose meter appropriately calibrated to screen glucose level in newborn;

- (k) Examination lighting device with a shatterproof bulb or protective shield;

- (l) Containers for soiled linen and waste materials which shall be closed or covered.

(2) A telephone or equivalent communication device must be accessible in the client care area.

(3) The licensee must clean, sterilize, disinfect and store equipment according to manufacturer guidelines and department requirements, if applicable. Clean and soiled equipment and supplies must be stored in separate areas.

(4) The applicant licensee shall provide and maintain infection control equipment and supplies for clinical staff.

NEW SECTION

WAC 246-329-140 Client records. The purpose of this section is to assure the center obtains, manages, and uses information to improve patient outcomes and the performance of the birth center in patient care.

(1) The birth center shall have a defined client record system, policies and procedures which provide for identification, security, confidentiality, control, retrieval, and preservation of client care data and information.

(2) The childbirth center must maintain a health record for each maternal and newborn client in a legally acceptable, integrated and chronological document on the licensee's standardized forms consistent with chapter 70.02 RCW, Medical records--Health care information access and disclosure. Each record must include:

(a) Client's demographic information and client identification to include at a minimum client's name, birth date, age, and address;

(b) Client's informed consent for care, service, treatment and receipt of the client bill of rights;

(c) Signed and authenticated notes describing the newborn and maternal status during prenatal, labor, birth, and recovery including, but not limited to:

(i) Documentation that verifies the client's low-risk maternal client status; and

(ii) Labor summary;

(iii) Newborn status including Apgar scores, maternal newborn interaction; and

(iv) Physical assessment of the mother and newborn during recovery;

(d) Documentation that a newborn screening specimen was collected (or signed refusal on the back of the specimen form) and submitted to the department's newborn screening program under WAC 246-650-020;

(e) Documentation and authentication of orders by clinical staff and birth center personnel who administer drugs and treatments or make observations and assessments;

(f) Laboratory and diagnostic testing results;

(g) Consultation reports;

(h) Referral, transfer of care, emergency transfer and transport documentation;

(i) Prophylactic treatment of the eyes of the newborn in accordance with WAC 246-100-206 (6)(b);

(j) Prenatal screening under chapters 70.54 RCW and 246-680 WAC, including client's refusal;

(k) Documentation of refusal of rapid HIV testing if documentation of an HIV test during prenatal care is not available;

(l) For HIV positive women, the antiretroviral medications during delivery and recommended lab tests;

(m) Intrapartum antibiotics for Group B Strep positive women per the CDC protocol;

(n) For Hepatitis B positive women, HBIG and Hepatitis B immunization for newborn;

(o) Refusal of any recommended test or treatment;

(p) Documentation of birth registration per chapter 70.58 RCW.

(3) For clients managed by a contractor in a birth center, the licensee shall ensure that each client record is maintained by the birth center and must contain the information as stated in subsection (2)(a) through (p) of this section. Services provided by the contractor, prior to the client's admission to the birth center, shall be summarized or placed in the record in their entirety.

(4) Entries in the client record shall be typewritten, retrievable by electronic means or written legibly in ink.

(5) Documentation and record keeping shall include:

(a) Completion of a birth certificate and, if applicable, a sentinel birth defect report under chapters 70.58 RCW and 246-491 WAC.

(b) Documentation of orders for medical treatment and/or medication. Each order shall be specific to the client and shall be authenticated, at the time the order is received, by an appropriate health care professional authorized to approve the order or medication.

(6) The licensee shall:

(a) Assure client records are kept confidential;

(b) Fasten client records together;

(c) Consider client records property of the birth center; and

(d) Provide a client access to their client record under the licensee's policy and procedure and applicable rules.

(7) When a client is transferred or discharged to another provider or facility, the birth center must provide a summary of care to the provider or facility to whom the client is transferred or discharged.

(8) The licensee shall maintain records for:

(a) Adults - three years following the date of termination of services; and

(b) Minors - three years after attaining age eighteen, or five years following discharge, whichever is longer.

(9) The licensee shall:

(a) Store records to prevent loss of information and to maintain the integrity of the record and protect against unauthorized use;

(b) Maintain or release records after a patient's or client's death according to chapter 70.02 RCW, Medical records--Health care information access and disclosure; and

(c) After ceasing operation, retain or dispose of records in a confidential manner according to the time frames in this subsection.

NEW SECTION

WAC 246-329-150 Pharmaceuticals. The purpose of this section is to assure that client pharmaceutical needs are met in a planned and organized manner.

(1) The licensee shall maintain written prescriptions or orders signed by a practitioner legally authorized to prescribe for all drugs administered to clients within the birth center.

(2) The licensee shall have written policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs.

(3) The licensee shall establish and implement written policies to address the type and intended use of any drug or device to be used by patients within the facility.

(4) The licensee shall assure that only local anesthetics are used.

(5) The licensee shall ensure:

(a) Drugs are only administered by personnel or clinical staff licensed to administer drugs;

(b) Drugs kept anywhere in the center are clearly labeled with drug name, strength, and expiration date;

(c) Expired drugs are removed from the storage units and destroyed properly;

(d) Drugs are stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons;

(e) Drugs for external use must be stored apart from drugs for internal use;

(f) Poisonous or caustic medications and materials including housekeeping and personal grooming supplies must show proper warning or poison labels and must be stored safely and separately from other medications and food supplies;

(g) Drugs requiring refrigeration must be kept in a separate refrigeration unit according to manufacturer's directions;

(h) Schedule II-IV controlled substances are:

(i) Kept in a separate locked storage unit; and

(ii) If heat sensitive, kept in a locked refrigeration unit;

(i) Schedule II-IV controlled substances no longer needed by the patient must be disposed of in compliance with chapter 246-865 WAC.

(6) If emergency drugs and intravenous fluids are maintained in the facility, these are considered an extension of the drug supply owned by the legally authorized prescribing practitioner; these drugs remain the responsibility of the legally authorized prescribing practitioner.

NEW SECTION

WAC 246-329-160 Birth center--Physical environment. The purpose of this section is to reduce and control environmental hazards and risks, prevent accidents and injuries, and maintain safe conditions and equipment for clients, visitors, and staff.

(1) The licensee shall provide and maintain a safe and clean environment. The licensee shall maintain the facility consistent with this chapter. Birthing centers built before the adoption of this chapter shall be maintained to the standards that were in place at the time the facility was licensed. If the licensee modifies or alters the facility, the altered areas must meet and be maintained consistent with this chapter and in accordance with the approved plans.

(2) The licensee shall provide at least one birthing room that is a minimum of three hundred square feet and has a minimum dimension of fifteen feet. The room shall be adequate and appropriate to provide for the equipment, staff, supplies, and emergency procedures required for the physical and emotional care of a maternal client, her support person or persons, and the newborn during birth, labor, and the recovery period.

(a) Additional birthing rooms shall have a gross floor space of one hundred fifty-six square feet or fourteen and one-half square meters and a minimum room dimension of eleven feet.

(b) The licensee shall locate birthing rooms to provide unimpeded, rapid access to an exit of the building which will accommodate emergency transportation vehicles.

(3) The licensee shall provide at least five square feet of fixed or portable work surface areas for use in the birthing room or rooms.

(4) The licensee shall provide and maintain toilet and bathing facilities.

(a) Toilet and lavatory shall be located in the vicinity of the birthing room or rooms.

(b) A bathing facility must be available for client use.

(c) The licensee shall keep clean and in good repair all floor surfaces, wall surfaces, water closets, lavatories, tubs, and showers.

(5) The licensee shall provide a space suitable for hanging full length garments and secure storage of clients' personal belongings and valuables.

(6) The licensee shall provide visual privacy for each maternal client and her support person or persons.

(7) The licensee shall assure hallways and doors providing access and entry into the birth center and birthing room or rooms are adequate width and conformation to accommodate maneuvering of ambulance stretchers and wheelchairs.

(8) Water supply. The licensee shall assure an adequate supply of hot and cold running water under pressure consistent with chapter 246-290 WAC, regarding public water supplies. The licensee shall provide and maintain equipment required to deliver hot water at point of use as follows:

(a) 120°F or less for handwash sinks and bathing fixtures;
(b) 160°F or more for laundry washers;
(c) 120°F or more for laundry washers using chemical sanitation;

(d) 120°F or more for mechanical dishwashers using chemical sanitation;

(e) 140°F or more for mechanical dishwashers using high temperature sanitation; and

(f) 180°F or more for sanitation cycle in high temperature mechanical dishwashers.

(9) The licensee shall provide heating and ventilation that:

(a) Provides a safe and adequate source of heat capable of maintaining a room temperature of at least 72°F.

(b) Provides ventilation sufficient to remove odors, excessive heat, and condensation.

(10) The licensee shall provide and maintain lighting and power and shall provide and maintain:

(a) Emergency lighting;

(b) General lighting and adequate examination lighting devices with shatterproof bulbs or protective shields, in the birthing room;

(c) Tamperproof electrical receptacles in birthing rooms, toilets, bathing facilities and family rooms and waiting areas; and

(d) Ground fault circuit interrupter (GFCI) receptacle when located within five feet of water source and above counters that contain sinks.

(11) The licensee shall assure linen and laundry service, and shall provide:

(a) Soiled linen/laundry storage and sorting areas physically separated from clean linen storage and handling areas, kitchen and eating facilities;

(b) Laundry services and shall include a commercial laundry service or the following equipment:

(i) Washing machine(s) providing hot water at a temperature of 160°F or 120°F for laundry washers using chemical sanitation;

(ii) Floor drains as required for equipment;

(iii) Dryer(s);

(iv) Dryer exhaust to the exterior; and

(v) A handwash sink.

(12) The licensee shall provide utility, housekeeping, garbage, and waste services and:

(a) Provide and maintain utility and storage facilities designed and equipped for washing, disinfecting, storing, and other handling of equipment and medical supplies in a manner which ensures physical segregation of clean and sterile supplies and equipment from those that are soiled and/or contaminated; and

(b) Assure all sewage, garbage, refuse, biomedical waste, human tissue, needles and sharps and liquid waste are collected and disposed of in a manner to prevent the creation of an unsafe or unsanitary condition.

(13) Medical gases. If oxygen is stored or used on the premises, the licensee shall, in addition to meeting other codes and regulations:

(a) Assure electrical equipment used in oxygen-enriched environments is designed for use with oxygen and is labeled for use with oxygen; and

(b) Post "no smoking" signs where oxygen is being administered.

(14) Food storage and/or preparation. The licensee shall not provide food preparation and service except when the birth center policy allows the preparation or storage of personal food brought in by the client or families of clients for consumption by that family. In this case, the licensee shall provide an electric or gas refrigerator capable of maintaining a temperature of 45°F or lower and if furnishing reusable utensils and dishes for client use, provide dishwashing facilities assuring hot water at a temperature of not less than 140°F or 120°F or more for mechanical dishwashers using chemical sanitation.

(15) The applicant may, as an alternate method for the design of new construction, use the 2006 edition of the *Guidelines for Design and Construction of Health Care Facilities* for the physical environment standards.

NEW SECTION

WAC 246-329-170 Emergency preparedness. The purpose of this section is to establish and implement a disaster plan designed to meet both internal and external disasters.

Each applicant or licensee shall:

(1) Develop and implement written policies and procedures governing emergency preparedness and fire protection;

(2) Develop an acceptable written plan, periodically rehearsed with personnel, contractors, and volunteers, to be followed in the event of an internal or external emergency, and for the care of casualties of the patient and family, personnel, contractors and volunteers arising from such emergencies; and

(3) Develop a fire protection plan to include:

(a) Instruction for all personnel, contractors or volunteers in use of alarms, fire fighting equipment, methods of fire containment, evacuation routes and procedures for calling the fire department and the assignment of specific tasks to all personnel, contractors and volunteers in response to an alarm; and

(b) Semiannual evacuation and fire drills for each shift of personnel.

NEW SECTION

WAC 246-329-180 Quality improvement. The purpose of this section is to ensure that performance improvement activities of clinical staff result in continuous improvement of client health outcomes.

Each childbirth center licensee must maintain a quality improvement program to assure the quality of care and services provided that includes, at a minimum:

(1) A complaint process that includes a procedure for the receipt, investigation, and disposition of complaints regarding services;

(2) A method to identify, monitor and evaluate:

(a) Services; and

(b) Referral, transfer, consultation, and transport experience and plans; and

(c) Complications of pregnancy, labor and postpartum; and

(d) Other aspects of services which affect quality care.

(3) A method to identify, evaluate, monitor and correct problems identified by clients, families, clinical staff, volunteers, students or consultants.

(4) A method to identify, evaluate, monitor and correct problems associated with events reported to the department in WAC 246-329-045 (3)(a) through (1) and (4)(a) and (b) as required by chapter 70.56 RCW.

(5) A method to monitor, evaluate and modify as needed corrective actions taken.

(6) A system to assess client satisfaction.

AMENDATORY SECTION (Amending WSR 05-13-189, filed 6/22/05, effective 7/23/05)

WAC 246-329-990 Fees. The purpose of the fees section is to describe the fees associated with licensing, renewal and other charges assessed by the department.

(1) Childbirth centers licensed under chapter 18.46 RCW shall submit an annual fee of five hundred eighty dollars and thirty cents to the department unless a center is a charitable, nonprofit, or government-operated institution under RCW 18.46.030.

(2) A change of ownership fee of one hundred fifty dollars. A new license will be issued and valid for the remainder of the current license period.

(3) The department may charge and collect from a licensee a fee of seven hundred fifty dollars for:

(a) A second on-site visit resulting from failure of the licensee to adequately respond to a statement of deficiencies;

(b) A complete on-site survey resulting from a substantiated complaint; or

(c) A follow-up compliance survey.

(4) A licensee shall submit an additional late fee in the amount of twenty-five dollars per day, not to exceed five hundred dollars, from the renewal date (which is thirty days before the current license expiration date) until the date of mailing the fee, as evidenced by the postmark.

(5) Refunds. The department shall refund fees paid by the applicant for initial licensure as follows:

(a) If an application has been received but no on-site survey or technical assistance has been performed by the department, two-thirds of the fees paid, less a fifty dollar processing fee((-));
or

(b) If an application has been received and an on-site survey or technical assistance has been performed by the department, one-third of the fees paid, less a fifty dollar processing fee.

~~(c) ((No fees paid by the applicant will be refunded if any of the following applies:))~~ The department may not refund applicant fees if:

(i) The department has performed more than one on-site visit for any purpose ((has been performed by the department));

(ii) One year has elapsed since an initial licensure application is received by the department, but no license is issued because applicant failed to complete requirements for licensure; or

(iii) The amount to be refunded as calculated by (a) or (b) of this subsection is ten dollars or less.

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 246-329-035	Criminal history, disclosure, and background inquiries.
WAC 246-329-040	Personnel, clinical staff, and volunteers who work directly with clients.
WAC 246-329-050	HIV/AIDS education and training.
WAC 246-329-060	Birth center policies and procedures.
WAC 246-329-070	Birth center equipment and supplies.
WAC 246-329-080	Records.
WAC 246-329-090	Pharmaceuticals.
WAC 246-329-100	Birth center--Physical environment.